UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION; STATE OF NEW YORK; STATE OF CALIFORNIA; STATE OF ILLINOIS; STATE OF NORTH CAROLINA; STATE OF OHIO; COMMONWEALTH OF PENNSYLVANIA; and COMMONWEALTH OF VIRGINIA,

Plaintiffs,

v.

VYERA PHARMACEUTICALS, LLC; PHOENIXUS AG; MARTIN SHKRELI, individually, as an owner and former director of Phoenixus AG and a former executive of Vyera Pharmaceuticals, LLC; and KEVIN MULLEADY, individually, as an owner and director of Phoenixus AG and a former executive of Vyera Pharmaceuticals, LLC,

Defendants.

Case No. 20-cv-00706 (DLC)

ECF Case

DEFENDANTS' MEMORANDUM ADDRESSING QUESTIONS OF LAW EXPECTED TO ARISE AT TRIAL

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Defendants Vyera Pharmaceuticals, LLC, Phoenixus AG, Kevin Mulleady, and Martin Shkreli respectfully submit this memorandum addressing questions of law expected to arise at trial. (ECF 409).

PRELIMINARY STATEMENT

Plaintiffs can be expected to focus their trial presentation on the price increase for Daraprim, and evidence that they will contend shows Defendants' intent to avoid generic competition. But charging higher prices, in and of itself, is not a violation of the antitrust laws, and anticompetitive intent—assuming Plaintiffs can prove such intent—is insufficient in the absence of actual harm to competition. *Verizon Commc'ns v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004); *K.M.B. Warehouse Distribs., Inc. v. Walker Mfg. Co.*, 61 F.3d 123, 130 (2d Cir. 1995). Plaintiffs' inability to prove that the challenged conduct caused such harm, as well as other critical gaps in their case, is fatal to each of their claims.

The Supreme Court has repeatedly identified a fundamental, threshold element under the rule of reason, which applies to each of Plaintiffs' claims in this litigation: Plaintiffs bear an initial burden of showing that the challenged conduct caused "a substantial anticompetitive effect that harms consumers in the relevant market." *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018); *see also NCAA v. Alston*, 141 S. Ct. 2141, 2160 (2021). Plaintiffs cannot meet that threshold burden here.

Specifically, Plaintiffs allege that Defendants Vyera Pharmaceuticals, LLC, Phoenixus AG (together, "Vyera"), and two of Vyera's former executives, Martin Shkreli and Kevin Mulleady (collectively with Vyera, "Defendants"), entered into three types of commercial arrangements that delayed the ability of generic manufacturers to obtain Food and Drug Administration ("FDA") approval to sell a generic form of the prescription drug Daraprim (used

to treat the parasitic infection toxoplasmosis). Those three types of challenged commercial arrangements are:

1) "class of trade" restrictions in Vyera's agreements with its distributors, which Plaintiffs allege made it more difficult for generic manufacturers to obtain brand Daraprim tablets they needed to conduct bioequivalence testing of their generic Daraprim products;

2) exclusive supply agreements between Vyera and two suppliers of pyrimethamine (the Active Pharmaceutical Ingredient ("API") in Daraprim), which Plaintiffs allege made it more difficult for generic manufacturers to obtain the pyrimethamine they needed to make generic Daraprim; and

3) provisions in Vyera's agreements with two of its four distributors that restricted the sale of data to third-party data aggregators, which Plaintiffs allege made it more difficult for generic manufacturers to assess the market opportunity for a generic Daraprim product.

Because there are now multiple FDA-approved generic versions of Daraprim on the market, Plaintiffs' only possible theory of harm to competition is delayed entry. In other words, Plaintiffs bear the initial burden of proving that the commercial arrangements challenged by the Amended Complaint caused anticompetitive effects by delaying FDA approval of generic forms of Daraprim. In addition, because the state Plaintiffs seek disgorgement as part of their remedy, Plaintiffs must establish the specific dates by which generic entry would have occurred "but for" the challenged conduct—otherwise there is no basis to calculate the equitable monetary relief that Plaintiffs seek.

As an initial matter, Plaintiffs cannot meet their threshold burden to prove that their alleged relevant product market of "FDA-approved pyrimethamine products" is properly defined. The evidence establishes that at least two other treatments for toxoplasmosis—Bactrim (also known as TMP-SMX) and compounded pyrimethamine—are therapeutically and economically interchangeable with Daraprim, and that Daraprim in fact lost as much as 70% of its sales to these competing products after Vyera increased the price of Daraprim in August 2015.

Beyond Plaintiffs' failure to prove the contours of the relevant market, however, none of Plaintiffs' experts—including their expert economist—even tries to meet Plaintiffs' burden of showing that Defendants' challenged conduct caused any delay in generic entry or harm to consumers. Instead, Plaintiffs' expert economist freely admits that he offers no opinion about whether the challenged conduct in fact delayed entry by any generic competitor. He further admits that his calculation of ill-gotten gains is based on assumed "but for" entry dates, and that he did not consider potential alternative causes of any delay. Assumptions and speculation, however, cannot satisfy Plaintiffs' burden of establishing that the challenged conduct delayed generic entry. Rather, Plaintiffs must meet their burden on causation with objective and reliable economic evidence, which is totally lacking here.

In addition to their failure to meet this threshold element of all their claims, Plaintiffs have failed to meet additional legal standards that apply to the specific types of commercial arrangements challenged in the Amended Complaint.

First, Plaintiffs' challenge to Vyera's exclusive agreements with two suppliers of pyrimethamine API requires Plaintiffs to show that those agreements resulted in substantial foreclosure of the market for pyrimethamine API. *See In re Keurig Green Mountain Single-Serve Coffee Antitrust Litig.*, 383 F. Supp. 3d 187, 234 (S.D.N.Y. 2019). Plaintiffs have provided no evidence—including from their expert economist—to meet this burden. Rather than substantial foreclosure, the evidence shows robust global competition in the market for pyrimethamine API supply that allowed generic manufacturers to obtain pyrimethamine from multiple sources, including from suppliers in the United States, [redacted], and India.

Second, because a manufacturer "generally has a right to deal, or refuse to deal, with whomever it likes, as long as it does so independently," Plaintiffs' challenge to the "class of

trade" provisions in Vyera's agreements with its distributors imposes additional burdens that Plaintiffs must meet. *See Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 761 (1984) (citation omitted). This is true whether those provisions are challenged as a conspiracy in restraint of trade under Section 1, as a unilateral refusal to deal under Section 2, or under Plaintiffs' parallel state-law claims. To support a challenge to the class of trade provisions under Section 1, Plaintiffs are required to show concerted action by the distributors with respect to those specific provisions. *See Anderson News, L.L.C. v. Am. Media, Inc.*, 680 F.3d 162, 183 (2d Cir. 2012); *Int'l Distrib. Ctrs., Inc. v. Walsh Trucking Co.*, 812 F.2d 786, 793–94 (2d Cir. 1987). But no such evidence exists. Rather, the evidence shows that Vyera acted unilaterally when it included the class of trade restrictions in its agreements with the distributors, as it is permitted to do under the law. *Monsanto*, 465 U.S. at 761.

To support a challenge to the same "class of trade" restrictions under Section 2 as a unilateral refusal to deal, Plaintiffs would have to fall within the narrow exception permitting such claims "only when a monopolist seeks to terminate a prior (voluntary) course of dealing with a competitor." *In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 134 (2d Cir. 2014) (citation omitted); *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 603 (1985). In other words, Plaintiffs would have to establish that Vyera had a prior, voluntary course of dealing in which it permitted open distribution of Daraprim without "class of trade" restrictions, and thereby sold Daraprim directly or indirectly to generic manufacturers. Plaintiffs cannot make that showing because Daraprim was already in specialty distribution and subject to "class of trade" restrictions in distribution agreements that Vyera inherited when it acquired the product. In fact, the evidence shows that Vyera *expanded* rather than contracted the distribution network for Daraprim after acquiring the product.

Third, Plaintiffs' challenge to provisions in two distribution agreements that restricted distributors from selling Daraprim sales data to third-party data aggregators makes so little sense that Plaintiffs did not even ask their own economist to address it. Plaintiffs' decision is understandable, because there simply is no legal or economic basis for a claim that *restrictions* on the disclosure of sales and pricing information to competitors could *harm* competition or result in antitrust liability. Even if there were a legal or economic basis for this theory, however, it is also wholly unsupported by any facts.

Fourth, Plaintiffs cannot prevail under a "monopoly broth" theory. If, as is the case here, none of the challenged commercial agreements violates the antitrust laws individually, Plaintiffs cannot conjure an antitrust violation by labeling them a "scheme" and mixing them together.

Finally, even if they had satisfied these fundamental legal elements of their claims, Plaintiffs would not be entitled to the equitable relief that they seek. The FTC is authorized to pursue permanent injunctive relief in federal court only where the defendant "is violating, or is about to violate" the law. 15 U.S.C. § 53(b). Plaintiffs cannot make that showing here for several reasons, but most self-evidently because the FDA has already approved generic Daraprim products submitted by three different generic manufacturers, in addition to the authorized generic product. In short, there is no evidence that Vyera is currently acting to delay generic competition to Daraprim. To the contrary, there is already healthy competition even in the market Plaintiffs have defined, and there is no evidence that Vyera is currently acting (or has plans to act) to delay additional generic competition to Daraprim or any product other than Daraprim.

The state Plaintiffs also seek the equitable monetary remedy of disgorgement, which requires them to establish the dates by which generic entry would have occurred "but for" the challenged conduct. Without reliable "but for" entry dates, however, there is no basis for the

experts or this Court to calculate the equitable monetary relief that Plaintiffs are seeking. Plaintiffs' economic expert does not offer "but for" entry dates for any of the generic manufacturers as part of his opinion. Rather, he "assumes" those dates based solely on the deposition testimony of two of the generic manufacturers concerning when they think their Abbreviated New Drug Applications ("ANDAs") might have been approved if they had been able to obtain API from their preferred supplier, and if they had been able to buy Daraprim samples at a time and price acceptable to them. That is nothing more than speculation. It is certainly not a reliable basis for the determination of "but for" entry dates—whether for determining liability or calculating equitable remedies.

LEGAL STANDARDS GOVERNING PLAINTIFFS' CLAIMS

Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), permits the FTC to bring a case in federal district court to enjoin conduct that "is violating, or is about to violate" Section 5 of the FTC Act, 15 U.S.C. § 45. The FTC alleges that Vyera's conduct violates Section 5 because it violates both Section 1 (Counts II and III) and Section 2 (Count I) of the Sherman Act. (Am. Compl. ¶¶ 314-22). The state Plaintiffs assert claims under parallel state statutes (Counts IV-X) based on the same factual allegations. (Am. Compl. ¶¶ 323-64).

A. Section 1 of the Sherman Act

Section 1 of the Sherman Act prohibits "[e]very contract, combination . . . or conspiracy, in restraint of trade or commerce among the several States." 15 U.S.C. § 1. To show a violation of Section 1, the FTC must prove: "(1) a combination or some form of concerted action between at least two legally distinct economic entities that (2) unreasonably restrains trade." *Geneva Pharms. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 506 (2d Cir. 2004); *see also Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 885 (2007). In a vertical market case like this one, where Plaintiffs do not (and cannot) allege that the challenged agreements are *per*

se unlawful, their claims are subject to the rule of reason, which requires this Court to "engage in a careful weighing of the competitive effects of the agreement—both pro and con—to determine if the effects of the challenged restraint tend to promote or destroy competition." *Geneva Pharms. Tech. Corp.*, 386 F.3d at 507.

Plaintiffs bear a significant initial burden under the rule of reason. To prevail on a rule of reason claim, a plaintiff must prove:

1) That the defendant had market power in a properly defined relevant market; and

2) That the challenged conduct has caused "a ***substantial anticompetitive effect*** that harms consumers in the relevant market."

Am. Express Co., 138 S. Ct. at 2284 (emphasis added) (quoting *Leegin*, 551 U.S. at 886); *see also 1-800 Contacts, Inc. v. FTC*, 1 F.4th 102, 114 (2d Cir. 2021) (under the rule of reason, "an antitrust plaintiff 'must demonstrate that a particular contract or combination is in fact unreasonable and anticompetitive before it will be found unlawful'" (quoting *Texaco Inc. v. Dagher*, 547 U.S. 1, 5 (2006))).

Only if the plaintiff meets that initial, threshold burden is the defendant required to "show a procompetitive rationale for the restraint." *Am. Express Co.*, 138 S. Ct. at 2284. If Defendants offer "a nonpretextual claim that [their] conduct is indeed a form of competition on the merits because it involves, for example, greater efficiency or enhanced consumer appeal—then the burden shifts back to [Plaintiffs] to rebut that claim," and if "the monopolist's procompetitive justification stands unrebutted, then [Plaintiffs] must demonstrate that the anticompetitive harm of the conduct outweighs the procompetitive benefit." *United States v. Microsoft Corp.*, 253 F.3d 34, 59 (D.C. Cir. 2001) (applying the rule of reason to a claim under Section 2); *see also Geneva Pharms. Tech. Corp.*, 386 F.3d at 506–07 (applying the rule of reason to a claim under Section 1).

B. Section 2 of the Sherman Act

A claim under Section 2 of the Sherman Act "has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966); *accord New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 651 (2d Cir. 2015). "To be condemned as exclusionary, a monopolist's act must have an 'anticompetitive effect.' That is, it must harm the competitive process and thereby harm consumers." *Microsoft Corp.*, 253 F.3d at 58; *accord New York v. Actavis, PLC*, No. 14-cv-7473, 2014 WL 7015198, at *38 (S.D.N.Y. Dec. 11, 2014) ("The plaintiff must demonstrate that the defendant's conduct had an anticompetitive effect." (citing *Microsoft Corp.*, 253 F.3d at 58)). The plaintiff must also show that the harm resulting from the allegedly monopolistic conduct occurred in the alleged relevant market. *See In re Mylan N.V. Sec. Litig.*, 379 F. Supp. 3d 198, 208 (S.D.N.Y. 2019). Here, Plaintiffs allege that Defendants' distribution agreements, exclusive API supply agreements, and agreements restricting the sale of sales data violate Section 2 of the Sherman Act. (Am. Compl. ¶ 318).

C. Section 5 of the FTC Act

Although Plaintiffs allege in their Amended Complaint that Defendants' conduct constituted "unfair methods of competition" in violation of Section 5 of the FTC Act, the Amended Complaint does not include a standalone claim under Section 5 apart from the claims under Sections 1 (Counts II and III) and 2 (Count I) of the Sherman Act. (Am. Compl. ¶¶ 318, 320, 322). Even if Plaintiffs had included a standalone claim under Section 5, however, an FTC Act Section 5 claim alleging that a particular practice constitutes an "unfair method[] of competition in or affecting commerce," 15 U.S.C. § 45(a)(1), requires a showing of harm to

competition similar to that required by the Sherman Act. *See FTC v. Raladam Co.*, 283 U.S. 643, 647–48 (1931) ("The paramount aim of the [FTC Act] is the protection of the public from the evils likely to result from the destruction of competition or the restriction of it in a substantial degree."); *accord E.I. du Pont de Nemours & Co. v. FTC*, 729 F.2d 128, 137–38 (2d Cir. 1984). Indeed, the FTC has recognized that Section 5 claims under the "unfair method of competition" prong of the FTC Act should be "evaluated under a framework similar to the rule of reason, that is, an act or practice challenged by the Commission must cause, or be likely to cause, harm to competition or the competitive process, taking into account any associated cognizable efficiencies and business justifications." FTC, *Statement of Enforcement Principles Regarding "Unfair Methods of Competition" Under Section 5 of the FTC Act*, at 1.

D. State Law Claims

The State of New York, the State of California, the State of Illinois, the State of North Carolina, the State of Ohio, the Commonwealth of Pennsylvania, and the Commonwealth of Virginia (collectively, "State Plaintiffs") assert claims under state law (Counts IV-X) based on the same factual allegations as the claims under Sections 1 and 2 of the Sherman Act. (Am. Compl. ¶¶ 323-64).[1] The state statutes and common law doctrines under which these claims are brought are modeled after the Sherman Act and are construed in light of federal precedent governing claims brought under the Sherman Act.[2]

[1] New York brings claims under the Donnelly Act, N.Y. GEN. BUS. LAW § 340 et seq. (Count IV(A)), and the New York Executive Law, N.Y. Exec. Law § 63(12) (Count IV(B)); California brings claims under the California Cartwright Act, Cal. Bus. & Prof. Code § 16700 et seq. (Count V(A)), and the California Unfair Competition Law, Cal. Bus. & Prof. Code § 17200 et seq. (Count V(B)); Illinois brings a claim under the Illinois Antitrust Act, Ill. Comp. Stat. 10/3(3) (Count VI); North Carolina brings a claim under the North Carolina Unfair or Deceptive Practices Act, N.C. Gen. Stat. § 75-1 et seq. (Count VII); Ohio brings a claim under the Ohio Valentine Act, Ohio Rev. Code Ann. § 1331 (Count VIII); Pennsylvania brings a claim under the common law doctrine against restraint of trade (Count IX(B)); and Virginia brings a claim under the Virginia Antitrust Act, Va. Code Ann. § 59.1 et seq. (Count X).

[2] The New York Donnelly Act is "modeled after the Sherman Act and should generally be construed in light of Federal precedent." *Biocad JSC v. F. Hoffmann-La Roche*, 942 F.3d 88, 101 (2d Cir. 2019) (citation

E. Plaintiffs' Burden on Market Definition

As an initial step, Plaintiffs "have the burden at trial of establishing the relevant product market." *Hayden Publ'g Co. v. Cox Broad. Corp.*, 730 F.2d 64, 68 (2d Cir. 1984). "The relevant market must be a market for particular products or services, the 'outer boundaries' of which 'are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it.'" *US Airways, Inc. v. Sabre Holdings Corp.*, 938 F.3d 43, 64 (2d Cir. 2019) (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962)). "'Interchangeability' looks to the use or function of the given product as compared to other products." *Bayer Schering Pharma AG v. Sandoz, Inc.*, 813 F. Supp. 2d 569, 575 (S.D.N.Y. 2011) (citation omitted). "'Cross-elasticity' is related to interchangeability, and

omitted). New York Executive Law Section 63(12) requires the New York Attorney General to prove that the alleged challenged conduct is in fact fraudulent or illegal, including because it violates Section 1 or Section 2 of the Sherman Act, which is what is alleged here. *See New York v. Feldman*, 210 F. Supp. 2d 294, 300 (S.D.N.Y. 2002) ("Violations of State laws, as well as violations of Federal laws or regulations, can constitute fraud or illegality within the meaning of Section 63." (quoting *State v. Stevens*, 497 N.Y.S.2d 812, 813 (N.Y. Sup. Ct. 1985))). The analysis of claims brought under California's Cartwright Act "mirrors the analysis under federal law because the Cartwright Act . . . was modeled after the Sherman Act." *Cnty. of Tuolumne v. Sonora Cmty. Hosp.*, 236 F.3d 1148, 1160 (9th Cir. 2001) (citation omitted). The claims brought under California's Unfair Competition Law are premised on the same challenged conduct giving rise to the claims brought under the Sherman Act, and are therefore subject to the same standards. *See Jones v. Micron Tech. Inc.*, 400 F. Supp. 3d 897, 923 (N.D. Cal. 2019). "The [Illinois Antitrust] Act expressly requires harmonization with federal antitrust law as interpreted by the federal courts, so Illinois courts interpret the state antitrust law in harmony with federal case law construing analogous provisions of federal legislation." *McGarry & McGarry, LLC v. Bankr. Mgmt. Sols., Inc.*, 937 F.3d 1056, 1062 (7th Cir. 2019) (citation omitted). Similarly, "because the North Carolina antitrust statutes track the language of the Sherman Act, the North Carolina Supreme Court has described the Sherman Act as 'instructive in determining the full reach' of the statutes." *Microsoft Corp. v. Comput. Support Servs. of Carolina, Inc.*, 123 F. Supp. 2d 945, 955 (W.D.N.C. 2000) (quoting *Rose v. Vulcan Materials Co.*, 194 S.E.2d 521, 530 (N.C. 1973)). The Ohio Valentine Act is patterned "in accordance with federal antitrust provisions" and "Ohio has long followed federal law in interpreting the Valentine Act." *Johnson v. Microsoft Corp.*, 834 N.E.2d 791, 794–95 (Ohio 2005). By its express terms, the Virginia Antirust Act "shall be applied and construed to effectuate its general purposes in harmony with judicial interpretation of comparable federal statutory provisions." *See* VA. CODE ANN. § 59.1-9.17. Finally, although Pennsylvania does not have a state antitrust statute, analysis of Pennsylvania common law restraint of trade claims "mirrors" the analysis under the Sherman Act because "the Sherman Act is merely the application of the common-law doctrine concerning the restraint of trade to the field of interstate commerce." *Yeager's Fuel, Inc. v. Pa. Power & Light Co.*, 953 F. Supp. 617, 668 (E.D. Pa. 1997) (citation omitted).

requires a consideration of the extent to which a change in the price of one product will alter demand for another product." *Id.* (citation omitted).

In the context of prescription drugs, courts assessing interchangeability look to the extent to which one drug has "similar effectiveness" and is therefore "readily substitutable" with another drug for the treatment of the underlying condition. *See, e.g.*, *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 435–36 (3d Cir. 2016) (citation omitted). The cross-elasticity analysis for prescription drugs focuses on the extent to which a change in the price of one drug (Drug X) affects the demand for that drug, as well as for other drugs (Drug Y) used to treat the same condition. *See, e.g.*, *Geneva Pharms. Tech. Corp.*, 386 F.3d at 496–99. If a price increase of Drug X causes sales of Drug X to decline and sales of Drug Y to increase, Drug X and Drug Y are said to show a high degree of cross-elasticity of demand, likely indicating that both Drug X and Drug Y are properly considered to be within the relevant product market. *See Mylan Pharms. Inc.*, 838 F.3d at 437.

F. Plaintiffs' Burden to Show Causation of Anticompetitive Effects

A showing of harm to competition is a required, threshold element of Plaintiffs' claims under Sections 1 and 2 of the Sherman Act, Section 5 of the FTC Act, and by extension Plaintiffs' state-law antitrust claims. *See, e.g.*, *Am. Express*, 138 S. Ct. at 2284 (the plaintiff in a Section 1 case must "prove that the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market"); *Alston*, 141 S. Ct. at 2160 (same); *Microsoft Corp.*, 253 F.3d at 58–59 (a showing that the challenged conduct "indeed has the requisite anticompetitive effect" and has "harmed competition, not just a competitor" is a required element under Section 2); *E.I. du Pont de Nemours & Co.*, 729 F.2d at 137 (the "unfair methods of

competition" prong of FTC Act Section 5 is appropriately employed to address conduct that "substantially lessens competition").[3]

A showing of competitive harm, standing alone, however, is insufficient; Plaintiffs must also prove a causal link between the challenged conduct and the actual and substantial competitive harm. *See Trinko*, 540 U.S. at 407; *Rambus Inc. v. FTC*, 522 F.3d 456, 464 (D.C. Cir. 2008); *see also Discover Fin. Servs. v. Visa U.S.A., Inc.*, 582 F. Supp. 2d 501, 503–04 (S.D.N.Y. 2008) ("It is well established that in order to succeed, an antitrust plaintiff must adhere to common law principles of causation." (citing *Cargill, Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 109–10 (1986))); *accord Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 535 (1983) (in antitrust cases, courts must "evaluate the plaintiff's harm, the alleged wrongdoing by the defendants, and the relationship between them"). This requirement applies to all of Plaintiffs' claims because "[a] lack of causation in fact is fatal to the merits of any antitrust claim." *Lavoho, LLC v. Apple, Inc.*, 232 F. Supp. 3d 513, 525 (S.D.N.Y. 2016) (Cote, J.), *aff'd sub nom. Diesel eBooks, LLC v. Simon & Schuster, Inc.*, 869 F.3d 55 (2d Cir. 2017).

Evidence of a causal link between the challenged conduct and actual harm to competition must be compelling and must tend to rule out other causal factors. *See In re Publ'n Paper Antitrust Litig.*, 690 F.3d 51, 66 (2d Cir. 2012) (an antitrust plaintiff must "demonstrate that [the

[3] The mere fact that consumers paid higher prices for brand Daraprim after Vyera raised the price of the product in August 2015 does not establish harm to competition because it does not show harm to the competitive process. *See NYNEX Corp. v. Discon, Inc.*, 525 U.S. 128, 136–37 (1998) (absent evidence that the defendant's conduct harmed the competitive process, the fact that the challenged conduct resulted in higher prices did not suffice to support antitrust claims); *accord Trinko*, 540 U.S. at 407 (charging higher prices, alone, "is not only not unlawful; it is an important element of the free market system"). Similarly, evidence of anticompetitive intent is irrelevant absent evidence of actual harm to competition. *See K.M.B. Warehouse Distribs.*, 61 F.3d at 130 ("[A]nticompetitive intent is not by itself sufficient to meet the adverse-effect requirement." (citing *Chi. Bd. of Trade v. United States*, 246 U.S. 231, 238 (1919))).

defendant's] conduct was a substantially or materially contributing factor in producing the injury," and must further establish that "the injuries alleged would not have occurred but for [the defendant's] antitrust violation" (citations omitted)); *cf. Boise Cascade Corp. v. FTC*, 637 F.2d 573, 578 (9th Cir. 1980) (declining to enforce an administrative order issued by the FTC in a Section 5 case on grounds that "the Commission has provided us with little more than a theory of the likely effect of the challenged . . . practices"). Speculation based on "general economic theory" or academic suppositions concerning what could or would happen but for the challenged conduct do not constitute actual evidence of adverse effects. *See Mil. Servs. Realty, Inc. v. Realty Consultants of Va., Ltd.*, 823 F.2d 829, 832 (4th Cir. 1987) (granting summary judgment where expert based his conclusion on general economic theory and did not conduct any quantitative analysis to determine the actual effect the challenged conduct had on competition); *see also Procaps S.A., Inc. v. Patheon, Inc.*, 845 F.3d 1072, 1085 (11th Cir. 2016) (experts' conclusions regarding the "theoretical" and "hypothetical" effects on competition were insufficient to establish harm to competition).

The fact that this case is brought by government plaintiffs also does not change Plaintiffs' burden on causation. In *American Express*, the Supreme Court unequivocally stated that, in a rule of reason case like this one, the government has the "burden to prove that the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market." 138 S. Ct. at 2284. The D.C. Circuit's decision in *Microsoft Corp.* compels no different result. The court in *Microsoft Corp.* rejected the defendant's argument that the government may prove causation only in one way—via "direct proof"—and noted only that it was unnecessary for the government to "reconstruct the hypothetical marketplace absent a defendant's anticompetitive conduct." 253 F.3d at 56–58, 79. *Microsoft Corp.* did not, however, relieve the government of

the burden of proving by a preponderance of the evidence that a defendant's conduct caused anticompetitive effects. To do so would have been error under Supreme Court precedent. *See Trinko*, 540 U.S. at 414 (only "exclusion[ary]" conduct violates the antitrust law). Rather, *Microsoft Corp.* confirmed that a government plaintiff—like a private plaintiff—"must demonstrate that the monopolist's conduct harmed competition, not just a competitor." 253 F.3d at 58–59. Indeed, the Ninth Circuit recently reversed a trial court's judgment in an antitrust case precisely because the FTC failed to meet that burden. *FTC v. Qualcomm Inc.*, 969 F.3d 974, 998 (9th Cir. 2020) (theory of anticompetitive harm offered by the FTC and adopted by the trial court incorrectly conflated antitrust liability and patent liability and improperly considered effects on the defendants' customers (high royalty rates), rather than effects on competition).

G. Standards Applicable to Specific Challenged Conduct

In addition to the general standards under Sections 1 and 2 of the Sherman Act and the analogous provisions of state antitrust law discussed above, there are specific legal standards that govern Plaintiffs' challenges to:

1) exclusive supply agreements between Vyera and two suppliers of pyrimethamine API used to make Daraprim; and

2) "class of trade" restrictions in Vyera's agreements with its distributors, permitting them to distribute Daraprim only to specialty pharmacies, hospitals, and other authorized classes of customers.

Challenges to these specific types of commercial arrangements under Sections 1 and 2 of the Sherman Act can be sustained only in very narrow circumstances because courts recognize that: 1) exclusive arrangements are often *procompetitive*; and 2) a commercial party such as a manufacturer "generally has a right to deal, or refuse to deal, with whomever it likes, as long as it does so independently." *Monsanto*, 465 U.S. at 761 (citation omitted).

i. Standards Applicable to Plaintiffs' Challenge to Exclusive API Supply Agreements

Exclusive supply agreements often "have pro-competitive purposes and effects, such as assuring steady supply, affording protection against price fluctuations, reducing selling expenses, and promoting stable, long-term business relationships." *Geneva Pharms. Tech. Corp.*, 386 F.3d at 508 (citing *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 333–35 (1961)). Exclusive supply agreements are thus "presumptively legal." *CDC Techs., Inc. v. IDEXX Labs., Inc.*, 186 F.3d 74, 80 (2d Cir. 1999) (citation omitted); *accord Microsoft Corp.*, 253 F.3d at 69 ("Permitting an antitrust action to proceed any time a firm enters into an exclusive deal would both discourage a presumptively legitimate business practice and encourage costly antitrust actions.").

Exclusive supply agreements may violate the antitrust laws only where they result in a "substantial foreclosure of competition" in the relevant market affected by the agreement. *In re Keurig*, 383 F. Supp. 3d at 234 (citation omitted); *see also Tampa Elec. Co.*, 365 U.S. at 328 (the competition foreclosed must "constitute a substantial share of the relevant market"). The FTC's own jurisprudence recognizes that "a proper analysis of exclusive dealing arrangements should take into account market definition, the amount of foreclosure in the relevant markets, the duration of the contracts, the extent to which entry is deterred, and the reasonable justifications, if any, for the exclusivity." *In re Beltone Elecs. Corp.*, 100 F.T.C. 68, 92 (1982).

In sum, Plaintiffs must establish that Vyera's exclusive supply agreements with two API suppliers resulted in substantial foreclosure in the global market for the pyrimethamine API used to make Daraprim. Moreover, determining "substantial foreclosure" in an API supply market requires careful analysis and consideration of—at a minimum[4]—the full range of potential API suppliers available to drug manufacturers, including suppliers that do not currently manufacture

[4] It must also take into account the ability of pharmaceutical companies to manufacture the API themselves.

the specific API in question but have the capability to do so. *Fresenius Kabi USA, LLC v. Par Sterile Prods., LLC*, 841 F. App'x 399, 404 n.12 (3d Cir. 2021).

ii. Standards Applicable to Plaintiffs' Challenge to "Class of Trade" Provisions in Distribution Agreements

Because a manufacturer "generally has a right to deal, or refuse to deal, with whomever it likes, as long as it does so independently," Plaintiffs' challenge to the "class of trade" provisions in Vyera's agreements with its distributors also imposes additional burdens that Plaintiffs must meet. *Monsanto*, 465 U.S. at 761 (citation omitted). This is true whether those provisions are challenged as a conspiracy in restraint of trade under Section 1, as a unilateral refusal to deal under Section 2, or under Plaintiffs' parallel state-law claims.

To support a challenge to the class of trade provisions under Section 1 of the Sherman Act (and, by extension, the parallel state antitrust statutes), "proof of joint or concerted action is required; proof of unilateral action does not suffice." *Anderson News*, 680 F.3d at 183. The mere existence of a contract between two or more parties is also insufficient. Rather, the plaintiff must prove "a plurality of actors agreeing to restrain trade." *Int'l Distrib. Ctrs.*, 812 F.2d at 794 (emphasis omitted). The evidence "must reveal a unity of purpose or a common design and understanding, or a meeting of minds in an unlawful agreement." *In re Elec. Books Antitrust Litig.*, 859 F. Supp. 2d 671, 681 (S.D.N.Y. 2012) (quoting *Monsanto*, 465 U.S. at 764).

To support a challenge to the same "class of trade" restrictions under Section 2 as a unilateral refusal to deal, Plaintiffs must fall within the narrow exception permitting such claims "only when a monopolist seeks to terminate a prior (voluntary) course of dealing with a competitor." *In re Adderall XR Antitrust Litig.*, 754 F.3d at 134 (citation omitted); *Aspen Skiing*, 472 U.S. at 603. In other words, Plaintiffs must establish (counterfactually) that Vyera terminated a prior, voluntary course of dealing in which it permitted open distribution of

Daraprim not subject to any "class of trade" restrictions, thus permitting indirect sales to generic manufacturers.

H. Standards Governing Equitable Remedies

If the FTC successfully proves a violation of Section 5 of the FTC Act, it must also establish that permanent injunctive relief is warranted under Section 13(b). Section 13(b) authorizes the FTC to pursue permanent injunctive relief in federal court only "in proper cases . . . and after proper proof." 15 U.S.C. § 53(b).

Injunctions are forward-looking remedies. *See United States v. W. T. Grant Co.*, 345 U.S. 629, 633 (1953) ("The purpose of an injunction is to prevent future violations."). Thus, all of Plaintiffs' claims require a showing that injunctive relief is necessary to stop harm to competition that is ongoing or is likely to recur (in which case the injunction will stop it). *Id.* (a permanent injunction is appropriate where the moving party shows that "there exists some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive"); *see also FTC v. Abbvie Inc.*, 976 F.3d 327, 380 (3d Cir. 2020) (a plaintiff seeking an injunction must prove a "cognizable danger" of a recurrent violation; proof that a recurrent violation is "merely possible" is insufficient); *FTC v. Evans Prods. Co.*, 775 F.2d 1084, 1087 (9th Cir. 1985) ("As a general rule, [p]ast wrongs are not enough for the grant of an injunction; an injunction will issue only if the wrongs are ongoing or likely to recur." (citation omitted)); *FTC v. Facebook, Inc.*, No. 20-cv-3590, 2021 WL 2643627, at *18 (D.D.C. June 28, 2021) (declining to award the FTC injunctive relief where the only actionable conduct occurred years prior to the filing of the complaint and where "no actionable violation is either ongoing or about to occur").

The State Plaintiffs' request for the equitable monetary remedy of disgorgement requires a separate and exacting showing of causation. As noted, "[i]t is well established that in order to

succeed, an antitrust plaintiff must adhere to common law principles of causation." *Discover Fin. Servs.*, 582 F. Supp. 2d at 503–04. For a plaintiff seeking equitable monetary relief or damages, this requirement includes identifying when the defendant's ill-gotten gains began to accrue. In cases alleging delayed generic competition, that requires establishment of a but-for entry date on which generic competition would have occurred but for the defendant's alleged anticompetitive conduct. *See* Areeda & Hovenkamp, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION § 2046g (5th ed. 2021) ("Areeda & Hovenkamp") ("Proof of delay is of course critical . . . because prices come down only when generic entry occurs. Thus, the difference between the entry date contemplated in the pay-for-delay settlement and the 'but for' entry date provides an important predicate for computing damages."); *see also In re Lidoderm Antitrust Litig.*, No. 14-md-2521, 2017 WL 679367, at *28 (N.D. Cal. Feb. 21, 2017) (noting that in an antitrust case alleging delayed generic competition, the trier of fact must "determine but-for dates and but-for prices").

APPLICATION OF LEGAL STANDARDS TO PLAINTIFFS' CLAIM

A. Plaintiffs Cannot Establish That the Challenged Conduct Caused Substantial Anticompetitive Effects.

Plaintiffs challenge three types of commercial arrangements entered into by the Defendants that Plaintiffs allege made it more difficult for generic manufacturers to obtain FDA approval for their generic Daraprim products:

1) "class of trade" restrictions in Vyera's agreements with its distributors that permitted those distributors to sell only to authorized classes of purchasers (including specialty pharmacies, hospitals, and certain government purchasers), which Plaintiffs allege made it more difficult for generic manufacturers to obtain the brand Daraprim they needed to do bioequivalence testing of their generic Daraprim products;

2) exclusive supply agreements between Vyera and two suppliers of pyrimethamine API—Fukuzyu and [redacted]—which Plaintiffs allege made it more difficult for generic manufacturers to obtain the pyrimethamine they needed to make generic Daraprim; and

3) provisions in Vyera's agreements with two of its distributors that prevented those distributors from selling Daraprim sales data to third party data aggregators, which Plaintiffs allege made it more difficult for generic manufacturers to assess the market opportunity for a generic Daraprim product.

Plaintiffs allege that the economic effect of these commercial arrangements was to delay generic competition to Daraprim, thereby allowing Defendants to reap monopoly profits at the expense of consumers. (Am. Compl. ¶ 8). As discussed above, in order to sustain claims based on those allegations at trial, Plaintiffs must first make two threshold showings:

1) that Vyera had market power in a properly defined relevant market; and

2) that the three types of challenged commercial arrangements caused a "***substantial anticompetitive effect***" that harmed consumers in that relevant market.

Am. Express Co., 138 S. Ct. at 2284 (emphasis added). As discussed in Part G *infra*, Plaintiffs cannot meet their burden of establishing market power in a properly defined relevant product market because the evidence shows that at least two other drugs are substitutable for Daraprim or generic Daraprim. But even under Plaintiffs' improperly narrow market definition, their claims would still fail because there is no evidence that the challenged conduct caused any delay in the market entry of generic Daraprim.

Four ANDAs for generic Daraprim have been submitted, and three of those have now been approved by the FDA:

Generic	ANDA Filed	Approved
Cerovene/Dr. Reddy's	5/8/2014	2/28/2020
[redacted]	[redacted]	[redacted]
Fera	12/19/2019	7/27/2021
Teva	1/27/2021	8/13/2021

In addition, a fifth generic manufacturer—Mylan—began developing a generic Daraprim product in 2015 but abandoned the effort before filing an ANDA.

To prevail under their theory, Plaintiffs must prove, *inter alia*, that ***but for*** the challenged conduct, one or more of the generic manufacturers identified above would have successfully obtained FDA approval and brought generic Daraprim to market sooner than they actually did. They must make this showing based on objective and reliable evidence; speculation and assumptions based on economic theory will not suffice. *See In re Publ'n Paper Antitrust Litig.*, 690 F.3d at 66; *cf. Boise Cascade Corp.*, 637 F.2d at 578.

Plaintiffs have made no meaningful attempt to meet this burden. Typically, antitrust plaintiffs rely on economic experts to provide evidence of anticompetitive effects. But Dr. Hemphill, Plaintiffs' economic expert, has disclaimed any opinion on whether the challenged conduct in fact produced anticompetitive effects. With respect to causation, Dr. Hemphill has clarified that he is "not offering an opinion on whether, as a factual matter, Vyera's restrictions made it more difficult for generics to obtain necessary inputs such as Daraprim samples and API" and is instead "offering the economic opinion that, if Vyera's restrictions did in fact have the alleged effect of impairing generics' ability to purchase Daraprim samples or pyrimethamine API, the restrictions were anticompetitive." (Corrected Reply Report of C. Scott Hemphill, Ph.D., J.D. ("Hemphill Reply") ¶ 99). This is nothing more than "general economic theory" and

"academic supposition"—exactly the type of evidence courts have recognized to be insufficient to meet a plaintiff's burden of showing anticompetitive effects. *See Mil. Servs. Realty, Inc.*, 823 F.2d at 832; *see also Procaps S.A., Inc.*, 845 F.3d at 1085.

Dr. Hemphill has also clarified that the "but for" entry dates for two of the generic manufacturers—Cerovene and Fera—that he used to calculate excess profits are not offered as part of his expert opinion. Dr. Hemphill did not determine those dates himself. Rather, they are simply assumptions based on the speculative testimony of two of the generic manufacturers about when they thought they might have been able to obtain FDA approval:

a) if they had been able to buy pyrimethamine API from their preferred API supplier and on their preferred schedule;

b) if they had been able to buy Daraprim samples from their preferred vendor on their preferred schedule and at their preferred price; and

c) if the FDA had taken the actions the generic manufacturers speculated they might have taken under different circumstances.

See Corrected Expert Report of C. Scott Hemphill, Ph.D., J.D. ("Hemphill Report") at 60-71). This is not evidence; it is just more speculation.

Like Dr. Hemphill, Plaintiffs' other expert witnesses also declined (or were unable) to opine that Defendants' challenged conduct in fact produced any anticompetitive effects. While Plaintiffs' experts are conspicuously silent on the question of causation and effects, however, the facts that will be introduced in evidence at trial are not, and they conclusively rebut each component of Plaintiffs' theory, as shown below.[5]

[5] Even if Plaintiffs could prove anticompetitive effects, the evidence at trial will demonstrate that any such effects (which are denied) are outweighed by the pro-competitive benefits of the challenged commercial agreements.

i. Plaintiffs Cannot Establish That Vyera's Distribution Agreements Harmed Competition

Plaintiffs' first theory is that Vyera's specialty distribution system, including the "class of trade" provisions in Vyera's distribution agreements, made it difficult for prospective generic competitors to obtain the samples of Daraprim that they needed to conduct bioequivalence testing. (Am. Compl. ¶ 4 ("Vyera's resale restrictions made it virtually impossible for generic companies to purchase sufficient quantities of Daraprim to conduct . . . FDA-required tests.")). Plaintiffs allege that difficulties in securing Daraprim samples delayed the submission of ANDAs and FDA approval of generic Daraprim. *Id.*

The record evidence shows that the generic manufacturers had opportunities to purchase the Daraprim samples they needed from multiple procurement firms that specialize in sourcing prescription drug samples for pharmaceutical manufacturers to use in drug development. Two of the generic manufacturers—Cerovene and Fera—made business decisions not to purchase all the samples they needed from these procurement firms, and instead [redacted]. Any delay they experienced waiting for the FDA to act on those waiver requests cannot be attributed to Vyera's agreements with its distributors. Another generic manufacturer—Teva—made the opposite business decision. It purchased the full amount of samples required by the FDA, and received prompt approval of its ANDA.

Cerovene

Any delays that Cerovene experienced in obtaining Daraprim samples were the result of intentional business decisions—first to delay contacting the procurement firm that it was told could source Daraprim, and then to buy only three bottles of Daraprim tablets instead of the five bottles it knew it needed.

- In February 2018, shortly after it learned it would need to conduct new bioequivalence testing, Cerovene was referred to [redacted], as being able to supply Daraprim samples. In emails dated February 12 and February 20, 2018, Dr. Reddy's, Cerovene's marketing partner, encouraged Cerovene to work with [redacted] to obtain the Daraprim samples needed to redo the bioequivalence testing. (GX 3395-002-004).

- It was not until September 2018, more than six months after Dr. Reddy's had first suggested that Cerovene contact [redacted], that Cerovene agreed to place a purchase order with [redacted] of Daraprim. (GX 3390-010-011).

- Cerovene purchased just three bottles [redacted], rather than the five bottles required to conduct the testing and meet the FDA's retention requirements, because Cerovene believed that the FDA either already had granted, or would grant, its request to conduct bioequivalence testing and satisfy the retention requirements using fewer than 500 tablets.

- Within approximately seven weeks of the purchase order, [redacted] obtained the three bottles of Daraprim that Cerovene had requested and delivered the bottles to Cerovene on or about November 19, 2018. (GX 3390-001; *see also* GX 3259).

- [redacted] (Tr. of Dep. of Manish Shah at 138:5 – 139:6).

There is no reason that Cerovene could not have placed a purchase order [redacted] at any time after February 12, 2018, when Dr. Reddy's first identified [redacted] as being able to provide Daraprim samples. Nor is there any reason that Cerovene could not have obtained the required five bottles of Daraprim, rather than ordering only three and waiting for the FDA to approve its request to conduct bioequivalence testing using fewer samples.

Fera

Plaintiffs allege that Fera "struggled to secure Daraprim samples to conduct bioequivalence testing." (Am. Compl. ¶ 248). The evidence, however, established that Fera had numerous opportunities to purchase Daraprim samples but turned them down because it hoped to

be able to purchase the samples at a lower price, or to [redacted]:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- When [redacted] delivered the two bottles to Fera, [redacted], offered to procure additional bottles of Daraprim for Fera. (GX 3056). [redacted] (DX 121).
- [redacted]
- [redacted]

There is no reason that Fera could not have placed a purchase order with [redacted] at any time after December 2016 when [redacted] first offered to source Daraprim samples for Fera. Nor is there any reason that Fera could not have obtained the required five bottles of Daraprim from [redacted] in January 2018, rather than ordering only two due to concerns about cost and based on the assumption that the FDA would approve its [redacted].

Mylan

At least five procurement companies offered to source Daraprim for Mylan, but Mylan did not pursue any of the offers and never placed a purchase order for Daraprim samples:

- On September 9, 2016, Mylan received an offer for Daraprim samples from a procurement company called Bionical Integrated Outsource Partners ("Bionical"). (DX 101). Mylan had no reason to believe that Bionical could not have sourced Daraprim samples, but it did not pursue the offer. (Tr. of Dep. of Michael Hatch at 160:12 – 162:6).

- On January 4, 2017, Mylan received a similar offer from Durbin PLC ("Durbin"). (DX 102). Durbin sent Mylan another offer on December 4, 2018, providing pricing information and stating that Durbin was "now frequently selling the Daraprim." (DX 254). Mylan had no reason to believe that Durbin could not have provided Daraprim samples, but it did not purchase Daraprim from Durbin in response to either offer. (Tr. of Dep. of Michael Hatch at 167:3 – 168:21).

- On September 25, 2017, Mylan received an offer for Daraprim samples from a pharmaceutical company called Premium Health Services, Inc. ("Premium"). (DX 107). Mylan had no reason to believe that Premium could not have sourced Daraprim samples, but it did not pursue the offer. (Tr. of Dep. of Michael Hatch at 184:16 – 185:20).

- Mylan received another offer for Daraprim samples on January 9, 2018 from a Canadian pharmaceutical procurement company called Globyz Biopharma Services ("Globyz"). (DX 110). Mylan had no reason to believe that Globyz could not have sourced Daraprim samples, but it did not pursue the offer. (Tr. of Dep. of Michael Hatch at 197:9 – 198:7).

- Mylan received another offer for Daraprim samples on January 17, 2018 from a procurement company called Spring Bio Solution Limited ("Spring Bio Solution"). (DX 111). Mylan had no reason to believe that Spring Bio Solution could not have sourced Daraprim samples, but it did not pursue the offer. (Tr. of Dep. of Michael Hatch at 199:7 – 201:21).

[redacted]

Plaintiffs cannot prove [redacted] ANDA was delayed as a result of an inability to obtain Daraprim samples for bioequivalence testing because [redacted] completed its bioequivalence testing in 2016 using Daraprim samples it purchased in 2014. (GX 0103-001).

Teva

Although Plaintiffs largely ignore Teva, Teva was able to source five 100-count bottles of Daraprim without difficulty from [redacted]:

- On October 4, 2018, Teva was contacted by [redacted], informing Teva that [redacted] had access to Daraprim samples. (DX 482 at Teva_FTC_Vyera_000012). This unsolicited offer was sent approximately six months before Teva made the decision to develop generic Daraprim.
- Teva subsequently placed an order with [redacted] for five 100-count bottles of Daraprim on August 28, 2019. (DX 257). [redacted] then placed a purchase order for the five bottles of Daraprim with [redacted] based pharmaceutical procurement firm. (DX 259).
- [redacted] obtained the five bottles from [redacted] promptly, and shipped them to Teva's facility in India on October 2, 2019, where Teva received them. (DX 261).

In sum, the evidence establishes that an entire industry of procurement firms exists to source Reference Listed Drug ("RLD") samples and that Cerovene, [redacted], Fera, Mylan, and Teva all had the ability to (and in fact did, except for Mylan, which never placed an order) obtain sufficient quantities of Daraprim to conduct bioequivalence testing. Thus, Plaintiffs cannot establish that any generic company was foreclosed from gaining access to Daraprim samples as a result of the challenged conduct.

ii. Plaintiffs Cannot Establish That Vyera's API Supply Agreements Harmed Competition

Plaintiffs' second theory is that Vyera "cut off competitors' access to pyrimethamine" by entering into exclusive API supply agreements with Fukuzyu and [redacted], causing prospective generic competitors to incur delays in securing supplies of API. (Am. Compl. ¶¶ 5-6). Plaintiffs have failed, however, to support their allegations with evidence that Vyera's API supply agreements with Fukuzyu and [redacted] resulted in any delay in the preparation, submission, or approval of ANDAs for generic Daraprim. The facts rebut this theory, including because each of the generic manufacturers had opportunities to negotiate supply agreements with Fukuzyu and

with [redacted] before Vyera entered its agreements with those suppliers in January 2017 and December 2017, respectively, and because none of them was foreclosed from obtaining pyrimethamine API from a wide range of suppliers in India, [redacted], and the United States. [redacted]

Plaintiffs suggest in the Amended Complaint (although they stop short of actually alleging) that Vyera's exclusive API supply agreement with [redacted] caused [redacted] to back out of an existing agreement with [redacted]. (Am. Compl. ¶ 232 ("[B]y this time, [redacted] was negotiating its exclusive contract with Vyera for pyrimethamine API and told [redacted] that it was 'no longer supporting' the company's ANDA.")). The evidence rebuts this suggestion. [redacted] declined to continue working with [redacted] in September 2017—three months ***before*** [redacted] entered into an exclusive agreement with Vyera in December 2017, and there is no evidence establishing (or even suggesting) that [redacted] decision had anything to do with Vyera. If anything, the timing suggests that [redacted] decision not to continue supporting [redacted] ANDA might have been to avoid violating [redacted].

- When the FDA issued its import ban on Ipca in 2015, [redacted] was forced to find a new API supplier. (GX 0103-002).
- During the summer of 2015, [redacted] began discussions with [redacted] concerning potential supply of pyrimethamine API. (Tr. of Dep. of [redacted] at 29:3-25). On February 17, 2017, [redacted] and [redacted] entered into a Preliminary Collaboration Agreement, pursuant to which [redacted] agreed to supply [redacted] with three different APIs—clomipramine, chlorpromazine, and pyrimethamine—in order to support [redacted] submission of ANDAs for those products. (GX 3166-002).
- [redacted] entered into its agreement with [redacted] approximately ten months ***before*** Vyera entered into its Distribution and Supply Agreement with [redacted] in December 2017. (GX 1108-012).
- In September 2017, [redacted] informed [redacted] that it would no longer support [redacted] ANDA for generic Daraprim. (Tr. of Dep. of [redacted] at 60:6 – 61:24).

- [redacted]

- In contrast, [redacted] decision not to support [redacted] ANDA for generic Daraprim in September 2017 occurred three months ***before*** Vyera entered into its Distribution and Supply Agreement with [redacted] in December 2017. (GX 1108-012).

- After [redacted] decision to no longer support [redacted] generic Daraprim ANDA, [redacted] began looking for a replacement API supplier. [redacted] turned to Bal Pharma, an Indian API supplier. (GX 0103-002).

- It took Bal Pharma approximately six months to develop pyrimethamine using [redacted] process, which [redacted] transferred to Bal Pharma following [redacted] decision to no longer support [redacted] ANDA. (Tr. of Dep. of [redacted] at 90:5-17).

Neither Vyera's agreement with Fukuzyu (which [redacted] had never even heard of) or its agreement with [redacted] prevented or delayed [redacted] from securing pyrimethamine. Rather, after incurring delays for reasons unrelated to Vyera, [redacted] was able to obtain pyrimethamine from Bal Pharma.

Cerovene

Plaintiffs allege that Vyera's exclusive API supply agreements hindered Cerovene's ability to secure pyrimethamine API in two ways. First, Plaintiffs suggest [redacted] walked away from an agreement in principle that it had negotiated with Cerovene [redacted] ***subsequently*** entered into an exclusive supply agreement with Vyera. (Am. Compl. ¶ 202 ("About six months after agreeing to supply Cerovene, however, [redacted] agreed to supply pyrimethamine to Vyera exclusively and not to any generic manufacturers for human use in the United States.")). Second, Plaintiffs allege that [redacted], and that this might threaten Cerovene's continued ability to

manufacture and sell generic Daraprim. (Am. Compl. ¶ 220 ("Even though Cerovene's generic Daraprim is currently being sold in the United States, Cerovene could soon face a supply disruption due to Vyera's exclusive API supply agreements. [redacted]

[redacted]:

- [redacted]
- After further negotiations between Cerovene [redacted], on September 9, 2016, Cerovene indicated that it wished to place an order [redacted] of pyrimethamine. (GX 3260-006).
- On October 4, 2016, [redacted] responded to Cerovene, through an intermediary, declining Cerovene's order because "demand [for pyrimethamine] is not expected to grow substantially since its usage is limited," [redacted] had determined "not to supply this item to anyone because of low business potential and high risk associated with the business." (GX 3260-001). [redacted] October 4, 2016 decision not to supply pyrimethamine API to Cerovene was made nearly three months ***before*** [redacted] into a Master Services Agreement with Vyera on January 25, 2017.
- On November 16, 2016, Cerovene and [redacted]
- Manish Shah, Cerovene's Co-Founder and President, testified [redacted] (Tr. of Dep. of Manish Shah at 237:4 – 238:22).
- Cerovene's entry into the [redacted] entered into a Distribution and Supply Agreement with Vyera in December 2017. (GX 1108).
- Between February 26, 2016 and November 14, 2017, [redacted]. (GX 0102-003). [redacted] (Tr. of Dep. of Manish Shah at 107:3-13).

- [redacted] pyrimethamine API to Cerovene for a period between 2017 and 2019, [redacted] (Tr. of Dep. of Manish Shah at 155:2 – 156: 11). In October 2019, Vyera terminated its agreement with [redacted], so this agreement cannot prevent Cerovene from obtaining pyrimethamine API from [redacted] in the future. *See* GX 1204.
- [redacted] decision not to supply pyrimethamine to Cerovene [redacted] did not delay Cerovene's ANDA because Cerovene had previously obtained all of the pyrimethamine API that it needed from [redacted] for bioequivalence testing and to support the launch of its generic Daraprim.
- [redacted]
- [redacted] was able to begin producing its first batch of pyrimethamine API in April 2019. This batch was completed approximately ten weeks later, in June 2019. (Tr. of Dep. of [redacted] at 35:4 – 48:9). Thus, it took [redacted] only approximately six months between when it started work on the project in December 2018 and when it was able to produce a finished batch of pyrimethamine.
- [redacted] has twenty-eight kilograms of pyrimethamine remaining from its initial production batch that is available for purchase. (Tr. of Dep. of [redacted] at 68:8 – 69:17).

Fera

Plaintiffs allege that Fera tried unsuccessfully to obtain pyrimethamine from [redacted]. Plaintiffs suggest (but again stop short of expressly alleging) that Vyera's exclusive supply agreement with [redacted] was the reason that [redacted] declined to work with Fera. (Am. Compl. ¶¶ 242; 245-46). The facts do not support Plaintiffs' theory:

- [redacted] This first communication occurred a year ***before*** Vyera's entry into the Master Services Agreement with Fukuzyu in January 2017.
- [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- Fera selected [redacted] as its pyrimethamine API supplier approximately seven months ***before*** Vyera entered into a Master Services Agreement with Fukuzyu on January 25, 2017 (GX 1020), and approximately eighteen months ***before*** Vyera entered into a Distribution and Supply Agreement with [redacted] in December 2017 (GX 1108-012).
- [redacted]
- [redacted] was able to manufacture pyrimethamine API for Fera despite not having a DMF or a pre-existing manufacturing process.

Mylan

Plaintiffs do not allege, and there is no evidence to suggest, that the challenged conduct hindered Mylan's ability to obtain pyrimethamine API. Rather, Mylan identified multiple potential API suppliers, twice obtained pyrimethamine from [redacted]

[redacted] then repeatedly turned down offers of additional quantities from [redacted] after it abandoned its generic Daraprim project:

- Mylan identified a number of potential API suppliers as early as February and March 2016, including Ipca, Fukuzyu, [redacted], and an Irish supplier called TopChem. (GX 3289; GX 3290-001).

- Mylan never contacted Fukuzyu, despite the fact that Fukuzyu was one of the API suppliers that Mylan identified in February 2016, eleven months ***before*** Vyera entered into its Master Services Agreement with Fukuzyu in January 2017. (Tr. of Dep. of Paula Raese at 82:10-13).

- Mylan ordered pyrimethamine API samples from [redacted] in March 2017 through [redacted]. (DX 97). Mylan received the samples on April 17, 2017. (DX 97). In July 2017, Mylan ordered an additional kilogram of pyrimethamine API from [redacted]. (DX 98). Mylan received this API in August 2017. (DX 99).

- Through [redacted], [redacted] offered to provide additional quantities of pyrimethamine API to Mylan on October 6, November 7, and November 13, 2017. (DX 99). Mylan responded by indicating that the generic Daraprim project "has been placed on hold." (DX 99). Mylan made no effort to obtain additional pyrimethamine API after the project was placed on hold in 2017. (Tr. of Dep. of Paula Raese at 108:7 – 109:10).

Teva

Plaintiffs do not allege that Teva had any difficulties obtaining pyrimethamine API because the evidence establishes that Teva was able to source pyrimethamine from a [redacted], without any difficulty at all. (DX 482 at Teva_FTC_Vyera_000013):

- Teva considered at least ten other potential API suppliers, including [redacted] (DX 482 at Teva_FTC_Vyera_000014).

- Teva's May 3, 2019 PowerPoint presentation launching its generic Daraprim project identified [redacted] as Teva's pyrimethamine API supplier and estimated that [redacted] would need only eight to twelve weeks of lead time to begin supplying pyrimethamine. (DX 484 at Teva_FTC_Vyera_0000255).

- Although [redacted]. (DX 482 at Teva_FTC_Vyera_000013). The fact that [redacted] ability to supply pyrimethamine to Teva.

In sum, the evidence establishes that Cerovene, [redacted], Fera, Mylan, and Teva all had the ability to (and in fact did) obtain access to pyrimethamine API, and [redacted] were able to quickly develop manufacturing processes for pyrimethamine.

iii. Plaintiffs Cannot Establish That Vyera's Restrictions on the Sale of Data Harmed Competition

Plaintiffs' third theory is that Vyera entered into agreements with two of its distributors that prevented the distributors from selling Daraprim sales data to IQVIA or to other third-party data aggregating firms. Plaintiffs allege that this had the effect of "obscuring" the market opportunity for generic Daraprim and "deter[ring]" generic manufacturers from pursuing development of generic Daraprim. (Am. Compl. ¶ 7). Plaintiffs specifically allege that these so-called "data blocking agreements" were put in place in 2017. (Am. Compl. ¶¶ 184-85).

There is simply no evidence to support this claim. The evidence establishes that prospective generic competitors were not dissuaded from filing ANDAs, and were able to fully assess the market opportunity—in most cases well ***before*** the data agreements even went into effect in 2017. Moreover, Plaintiffs' expert economist expressly disavowed any attempt to establish a causal connection between the data agreements and any delay in generic entry. (Hemphill Report at 55, n.221 (explaining that Professor Hemphill was not "asked to opine on the anticompetitive effects resulting specifically from Vyera's data-blocking agreements") and 60, n.238 (stating that Professor Hemphill "was not asked to separately quantify excess profits from Vyera's data-blocking agreements")). None of Plaintiffs' other expert witnesses offer such an opinion, and there is no documentary evidence or credible lay witness testimony establishing a causal connection between the challenged data agreements and any delay to generic competition.

[redacted]

Plaintiffs do not allege that data restrictions in Vyera's distribution agreements hindered [redacted] ability to assess the market opportunity for generic Daraprim, and the evidence would not support such an allegation:

- [redacted] decided to develop a generic version of Daraprim in 2014, before Vyera had even acquired the product and three years before the provisions restricting data sales were included in two of Vyera's distribution agreements. (Tr. of Dep. of [redacted] at 18:2 – 19:6).
- [redacted] did not have a subscription to IQVIA or to any other source of pharmaceutical sales data, but obtained IQVIA data for Daraprim from one of its marketing partners in 2013 or 2014 showing annual sales of approximately one million tablets. (Tr. of Dep. of [redacted] at 122:19 – 123:11).
- After reviewing Daraprim sales data from IQVIA in 2013 or 2014, [redacted] did not attempt to review updated IQVIA data or to conduct further market research. (Tr. of Dep. of [redacted] at 138:14-24; 155:6 – 159:13).

Cerovene

Similarly, Plaintiffs do not allege, and no evidence even suggests, that the challenged restrictions on the sale of Vyera's Daraprim data hindered Cerovene's ability to assess the market opportunity for generic Daraprim.

- [redacted]
- [redacted]

Fera

Plaintiffs also do not allege, and no evidence even suggests, that Vyera's agreements with its distributors with respect to Daraprim sales data hindered Fera's ability to assess the market opportunity for generic Daraprim:

- [redacted]

- [redacted]

Mylan

Mylan is the only generic manufacturer that Plaintiffs allege was in any way hindered by the agreements imposing restrictions on the sale of Daraprim sales data. (Am. Compl. ¶ 266 ("[Mylan] cited its inability to get a 'real sense' of Daraprim's sales because the product was 'no longer reported in [IQVIA]' as a reason for abandoning the project.")). The evidence establishes, however, that Mylan made the decision to enter the market in 2015—long before Vyera's agreements placing restrictions on the sale of Daraprim sales data by two of its distributors were allegedly entered into in 2017.

- In 2015, Mylan decided to develop generic Daraprim based, in part, on IQVIA data from June 2015 showing sales of approximately $9.1 million per year. (GX 3111-002). Mylan estimated at the time that Daraprim could have peak sales of $22.1 million. (GX 3111-002).

- In or around September 2015, Mylan developed a market assessment showing anticipated revenues based on different potential pricing, volume, and market share assumptions. (DX 94). This forecast estimated annual Daraprim sales of 558,000 tablets, and projected a downward trend in sales from 2015 forward. (DX 94).

- Thereafter, Mylan invested little in generic Daraprim and denoted the project as having "low internal priority" before putting it on hold in 2017. (DX 103). These decisions were made *before* Vyera's data agreements were allegedly entered into.

Teva

Teva was also able to develop a thorough understanding of the market opportunity, even though it conducted its assessment in 2019, two years after the challenged provisions were included in two of Vyera's distribution agreements:

- Teva used what it described as its "sophisticated market research team" to assess "competitive intelligence[] gathered from pharmacies" and to conduct "specialized research." (DX 482 at Teva_FTC_Vyera_000011). On this basis, Teva concluded that "the market for a generic [Daraprim] [was] attractive to Teva from a commercial perspective." (DX 482 at Teva_FTC_Vyera_000011).

- Teva's sophisticated understanding of the market opportunity is further reflected in a May 3, 2019 PowerPoint presentation that Teva prepared shortly after deciding to develop generic Daraprim. The PowerPoint comprehensively detailed Teva's forecasts and strategy for obtaining FDA approval. (DX 484 [Teva_FTC_Vyera_000244-67]).

- Teva subsequently updated its forecasts several times, in November 2019, March 2020, and September 2020, to reflect the progression of Teva's ANDA, as well as the FDA's approval of Cerovene's ANDA. (DX 485, DX 486, DX 487 [Teva_FTC_Vyera_0000269-71]).

In sum, the evidence established that [redacted], Cerovene, Fera, and Mylan made the decision to enter the market long before Vyera's entry into agreements with two of its distributors limiting their ability to sell Daraprim sales data, that Teva was able to develop a comprehensive understanding of the market opportunity in 2019, notwithstanding those agreements, and that—if anything—a number of the generic manufacturers overestimated the volume of Daraprim being sold, which created an added incentive to file an ANDA rather than discouraging generic companies from deciding to compete.

B. Any Delay in Generic Entry Was Caused by Factors Unrelated to the Challenged Conduct

As noted above, the plaintiff in an antitrust case must satisfy basic common law elements of causation. *See Discover Fin. Servs.*, 582 F. Supp. 2d at 503–04. Thus, it is axiomatic that when the plaintiff's injury was caused by something other than the defendant's challenged conduct, there can be no finding of causation. *See id.* at 504–05 ("[A] plaintiff must have proved that some damage occurred to it as a result of defendant's alleged antitrust violation, and not some other cause. . . . [I]f . . . that plaintiff's injury was caused primarily by something other than the alleged antitrust violation, . . . that plaintiff has failed to prove that it is entitled to recover damages from defendant." (quoting ABA Section of Antitrust Law, Model Jury Instructions in Civil Antitrust Cases (2005) at F-3)); *see also In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 652–53 (E.D. Mich. 2000) ("Simply put, when an independent cause fully accounts for

the plaintiff's alleged antitrust injury, it breaks the causal connection between the alleged antitrust violation and the plaintiff's injury.").

To the extent that any of the prospective generic competitors that Plaintiffs identify in their Amended Complaint—Cerovene, [redacted], Mylan, or Fera—experienced delays in submitting or obtaining FDA approval for their generic Daraprim ANDAs, those delays were caused not by the challenged conduct but by factors entirely unrelated to Defendants.

[redacted]

Any delay in the FDA's approval of [redacted] ANDA is directly attributable to (1) the Ipca import ban, which required [redacted] to find a new API supplier, (2) [redacted] delays in filing a DMF for pyrimethamine between 2015 and 2017, as well as [redacted] decision to stop supporting [redacted] ANDA (both of which occurred before [redacted] entered into an agreement with Vyera), and (3) more recent delays attributable to COVID.

Cerovene

Any delay in the FDA's approval of Cerovene's ANDA is attributable to [redacted], which required Cerovene to find a new API supplier and, because Cerovene had conducted its bioequivalence testing [redacted], led the FDA to direct Cerovene to redo its bioequivalence testing, and (2) Cerovene's intentional cost-cutting measure to purchase fewer than the required number of Daraprim samples and [redacted].

Fera

Any delay in the submission or approval of Fera's ANDA is directly attributable to (1) [redacted] failure to meet its projected timeline for developing a pyrimethamine manufacturing process and (2) Fera's own intentional decision to purchase fewer than the required number of

bottles of Daraprim from [redacted] so that Fera could cut costs by attempting to [redacted].

Mylan

The challenged conduct did not contribute to Mylan's decision to abandon its generic Daraprim project. Rather, Mylan elected to terminate the project after determining that it would produce a low return on investment.

That any setbacks or delays experienced by Cerovene, [redacted], Fera, and Mylan were unrelated to the challenged conduct is further confirmed by Teva's experience. Teva assessed the market, secured an API supplier, and sourced Daraprim samples without difficulty—obtaining FDA approval of its generic Daraprim ANDA in August 2021, with barely two years elapsing between project inception and ANDA approval. This is presumably why neither Plaintiffs nor their experts address the evidence concerning Teva at all. In fact, none of Plaintiffs' experts even attempts to address the alternative causes of any delays encountered by Cerovene, [redacted], or Fera. This failure significantly undermines the credibility of their conclusions, which are already impermissibly unreliable because they are based solely on assumptions and speculation. *See U.S. Info. Sys., Inc. v. Int'l Bhd. of Elec. Workers Local Union No. 3*, 313 F. Supp. 2d 213, 238 (S.D.N.Y. 2004) ("An expert must demonstrate that he has adequately accounted for obvious alternative explanations in order for his testimony to be reliable. Before a conclusion on causation can be reliably drawn, the expert must make some reasonable attempt to eliminate some of the most obvious causes." (citations omitted)).

C. Plaintiffs Cannot Prevail Under a "Monopoly Broth" Theory

Having failed to establish that either Vyera's distribution practices, its API supply agreements, or its agreements restricting the sale of Daraprim sales data independently

constitutes unlawful exclusionary conduct, Plaintiffs cannot transform that separately lawful conduct into an antitrust violation by packaging it as a single scheme. Separate acts that do not independently rise to the level of an antitrust violation cannot be analyzed together to create a cause of action. For instance, in *City of Groton v. Connecticut Light & Power Co.*, 662 F.2d 921 (2d Cir. 1981), the Second Circuit held that multiple antitrust claims, each of which was not viable on its own, could not be cobbled together to create a single viable claim. *Id.* at 928–29; *see also Eatoni Ergonomics, Inc. v. Rsch. in Motion Corp.*, 486 F. App'x 186, 191 (2d Cir. 2012) ("Because the[] alleged instances of misconduct are not independently anti-competitive, we conclude that they are not cumulatively anti-competitive either."); *City of Mishawaka, Ind. v. Am. Elec. Power Co.*, 616 F.2d 976, 986 (7th Cir. 1980) (describing the plaintiff's attempt to "mix . . . the various ingredients of . . . behavior in a monopoly broth that produces [an] unsavory flavor"); *Simon & Simon, PC v. Align Tech., Inc.*, No. 19-cv-506, 2020 WL 1975139, at *8 (D. Del. Apr. 24, 2020) ("Plaintiff's characterization of [defendant's] otherwise non-actionable refusals to deal as a 'scheme' do not save its claims.").

The Supreme Court applied this rule in *Pacific Bell Telephone Co. v. linkLine Communications, Inc.*, refusing to combine a deficient duty-to-deal claim and a deficient predatory pricing claim (i.e., independently meritless claims) to create a single viable antitrust claim in that case. 555 U.S. 438, 450 (2009) (citing *Trinko*, 540 U.S. at 410). Specifically, the Supreme Court held that the alleged high wholesale and low retail prices could not be evaluated together under a monopoly broth theory despite their necessary connection in the plaintiff's theory of harm. *Id.* at 452. The Supreme Court explained that the plaintiff's "price-squeeze claim, looking to the relation between retail and wholesale prices, [was] nothing more than an amalgamation of a meritless claim at the retail level and a meritless claim at the wholesale

level." *Id.* Thus, the Supreme Court reasoned that two independently lawful acts (or meritless claims) could not be combined to conjure an antitrust violation.

In short, although Plaintiffs seek to cast the allegations of restricted distribution, exclusive API supply agreements, and restrictions on the sale of data as part of a "comprehensive scheme," (Am. Compl. ¶ 1), because none of the three components of that alleged "scheme" is alone sufficient to state an antitrust claim, Plaintiffs cannot satisfy their burden merely by mixing them together. *See Eatoni Ergonomics, Inc. v. Rsch. In Motion Corp*., 826 F. Supp. 2d 705, 710 (S.D.N.Y. 2011), *aff'd*, 486 F. App'x 186 (the plaintiff "does not, and cannot, cite any authority for the proposition that a series of unilateral acts that do not violate the antitrust laws may be aggregated into an unlawful 'course of conduct'").

D. Plaintiffs Cannot Establish That the Challenged Conduct Resulted in Substantial Foreclosure of the Market for Pyrimethamine API

As discussed above, in order to prevail on their challenge to Vyera's exclusive API supply agreements with Fukuzyu and [redacted], Plaintiffs bear an additional burden of showing that those agreements resulted in substantial foreclosure of the market for pyrimethamine API. That is because exclusive supply agreements are often procompetitive, "assuring steady supply, affording protection against price fluctuations, reducing selling expenses, and promoting stable, long-term business relationships." *Geneva Pharms. Tech. Corp.*, 386 F.3d at 508 (citing *Tampa Elec. Co.*, 365 U.S. at 333–35). As a result, they are presumptively lawful, and subject to challenge under Section 1 only if they are shown to cause "substantial foreclosure" in the affected market. *In re Keurig*, 383 F. Supp. 3d at 234 (citation omitted); *see also Tampa Elec. Co.*, 365 U.S. at 328 (the competition foreclosed must "constitute a substantial share of the relevant market").

The market affected by Vyera's supply agreements with Fukuzyu and [redacted] is the global market for pyrimethamine API supply. As the Third Circuit recently explained, for purposes of determining substantial foreclosure, an API supply market potentially includes API suppliers that have filed DMFs for pyrimethamine and API suppliers that have not. *Fresenius Kabi USA*, 841 F. App'x at 404 n.12. It includes API suppliers that already manufacture pyrimethamine for use in the United States or in other countries, and suppliers that have never manufactured pyrimethamine before but have the capability to do so. *Id.* It potentially includes all of the API suppliers that the generic manufacturers in this case considered, and it certainly includes all those that they selected, including [redacted], Bal Pharma and [redacted] in India, and [redacted] in the United States. Given this evidence, it is not surprising that Plaintiffs' expert economist does not provide an opinion that the challenged API supply agreements resulted in substantial foreclosure.

E. Plaintiffs Cannot Establish an Antitrust Duty to Deal

Plaintiffs allege that Vyera imposed "class of trade" restrictions on its distributors allowing them to distribute Daraprim only to authorized customers, including specialty pharmacies, hospitals, and government purchasers, and that they did so to "prevent[] generic companies from purchasing Daraprim" and to "deny[] them the ability to conduct the bioequivalence testing necessary for FDA approval." (Am. Compl. ¶ 99). This theory incorrectly presupposes that Vyera was under an obligation to sell Daraprim to its competitors when, in fact, no such obligation existed. And absent an antitrust duty to deal, Plaintiffs' challenge to the "class of trade" provisions in the distribution agreements fails because "the Sherman Act 'does not restrict the long recognized right of [a] trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal.'" *Trinko*, 540 U.S. at 408 (quoting *United States v. Colgate & Co.*, 250 U.S.

300, 307 (1919)); *see also Oreck Corp. v. Whirlpool Corp.*, 579 F.2d 126, 133 (2d Cir. 1978) ("It has always been the prerogative of a manufacturer to decide with whom it will deal.").

There is one narrow exception to the right of a manufacturer to freely choose with whom it will deal that "comes into play only when a monopolist seeks to terminate a prior (voluntary) course of dealing with a competitor." *In re Adderall XR Antitrust Litig.*, 754 F.3d at 134 (citation omitted); *accord Aspen Skiing*, 472 U.S. at 603 (liability for refusing to deal with a competitor may arise only where "the monopolist elected to make an important change in a pattern of distribution that had originated in a competitive market and had persisted for several years"). As the Supreme Court has observed, this is the sole exception, and courts have been "very cautious" about recognizing others. *Trinko*, 540 U.S. at 408.

Recent refusal to deal claims brought against Facebook by the FTC and a number of State Attorneys General in the U.S. District Court for the District of Columbia provide helpful explanation. In *Facebook*, the plaintiffs alleged that Facebook violated antitrust law by conditioning the availability of application programming interfaces to software developers on the condition that the developers agree that their apps would not compete with Facebook. *See* 2021 WL 2643627, at *5. The court held that Facebook's decision to not make the programming interfaces available to prospective competitors, especially those with which Facebook had not previously shared programming interfaces, was not actionable. *See id.* at *17 ("[I]t is clear off the bat that Facebook's adoption of a policy of not offering . . . access to competitors did not, standing alone, violate Section 2. . . . Facebook's general policy of withholding . . . access from competitors . . . was plainly lawful to the extent it covered rivals with which it had no previous, voluntary course of dealing."). "Rather, to be actionable, an unlawful refusal-to-deal scheme

would have to be made up of refusals that were themselves independent violations of the Aspen Skiing test." *Id.*

The circumstances that would give rise to an antitrust duty to deal under this standard are not present here. To establish a "voluntary" course of dealing, Plaintiffs must show that Vyera had previously been in the practice of selling Daraprim to prospective generic competitors, either directly or through its distributors. However, there is no evidence to support this conclusion. In fact, the evidence establishes the opposite. The prior owners of Daraprim included "class of trade" provisions in their distribution agreements with Walgreens and ICS that Vyera inherited when it acquired Daraprim. In fact, Vyera actually *expanded* the distribution network for Daraprim after acquiring the product, and it certainly never terminated a preexisting practice of selling directly or indirectly to generic manufacturers, or to any categories of purchasers other than those identified as authorized purchasers in the "class of trade" provisions.

F. Plaintiffs Cannot Establish Concerted Anticompetitive Conduct

Plaintiffs also cannot sustain their claims merely by characterizing them as a conspiracy, because there is no evidence of any concerted action by Vyera's distributors or its API suppliers with respect to the challenged provisions. *See Simon & Simon*, *PC*, 2020 WL 1975139, at *8 ("Plaintiff's characterization of [defendant's] otherwise non-actionable refusals to deal as a 'scheme' do not save its claims."). Plaintiffs assert the existence of a conspiracy in violation of Section 1 and its state-law analogues based merely on the fact that Vyera had contracts with its distributors containing class of trade restrictions and contracts with its API suppliers containing exclusivity provisions. Plaintiffs, however, can offer no evidence of concerted anticompetitive conduct between Vyera and its distributors or API suppliers that could give rise to Section 1 liability.

To establish a violation of Section 1 and, by extension, the parallel state antitrust statutes, "proof of joint or concerted action is required; proof of unilateral action does not suffice." *Anderson News*, 680 F.3d at 183. The mere existence of a contract between two or more parties is insufficient. Rather, Plaintiffs must prove "a plurality of actors agreeing to restrain trade." *Int'l Distrib. Ctrs., Inc.*, 812 F.2d at 794 (emphasis omitted). In other words, the allegations "must reveal a unity of purpose or a common design and understanding, or a meeting of minds in an unlawful agreement." *In re Elec. Books Antitrust Litig.*, 859 F. Supp. 2d at 681 (quoting *Monsanto Co.*, 465 U.S. at 764).

However, there is no evidence that the counterparties to its agreements—Vyera's distributors and API suppliers—shared (or were even aware of) Vyera's alleged anticompetitive intent. Plaintiffs thus cannot establish the requisite "unity of purpose," "common design and understanding," or "meeting of the minds in an unlawful agreement." *In re Elec. Books Antitrust Litig.*, 859 F. Supp. 2d at 681; *accord Toscano v. Prof'l Golfers Ass'n*, 258 F.3d 978, 984 (9th Cir. 2001) (affirming summary judgment on Section 1 claims where, as here, the contract counterparties "had no involvement in the establishment or enforcement of the allegedly anticompetitive provisions of the contracts," but rather "merely accepted them" without any evidence of a "'conscious commitment to a common scheme designed to achieve an unlawful objective'") (quoting *Monsanto*, 465 U.S. at 764); *Am. Airlines v. Christensen*, 967 F.2d 410, 413–14 (10th Cir. 1992) (affirming summary judgment for defendant airline where "[n]o evidence in the record suggest[ed] that American did not independently set the terms under which it would offer its travel awards, and the mere fact that its members accepted those terms does not generate the kind of concerted action needed to violate Section 1").

Judge Marrero's handling of *Merced Irrigation District v. Barclays Bank PLC* provides helpful guidance. *See* 165 F. Supp. 3d 122 (S.D.N.Y. 2016). There, the plaintiff, an irrigation district located in California, brought a class action against a financial services company alleging that the defendant engaged in an unlawful conspiracy to manipulate electricity prices. *Id.* at 128. The allegation of a conspiracy was premised on the defendant's entry into a series of daily electricity "swap" contracts with third parties. *Id.* at 138. Judge Marrero held that those facts were insufficient under Section 1 because there was no evidence that the defendant's counterparties shared any anticompetitive intent; rather, "[t]he only 'meetings of the minds' alleged in the Complaint . . . [were] agreements between parties acting independently to buy or sell electricity—even if [defendant] had an ultimately anticompetitive purpose in mind." *Id.* at 139. Thus, Judge Marrero dismissed the Section 1 claim, reasoning that he was "not persuaded that the mere existence of a series of contracts between a defendant and . . . counterparties in the service of the defendant's unilateral scheme constitutes an agreement to unreasonably restrain trade under Section 1 of the Sherman Act." *Id.* at 139–40.[6]

Even had Plaintiffs proven a shared anticompetitive intent between Vyera and some or all of its distributors, or between Vyera and either or both of its API suppliers—which they have failed to do—their claims would still fail for the independent reason that Plaintiffs have offered

[6] A 2014 decision from the District of New Jersey applied these principles to a set of virtually identical facts to those alleged here. In *Mylan Pharms. v. Celgene Corp.*, No. 14-cv-2094, 2014 WL 12810322 (D.N.J. Dec. 23, 2014), the defendant held the rights to two brand name drugs. *Id.* at *1. The plaintiff desired to develop generic forms of the drugs but alleged that it could not obtain samples because the defendant had entered into agreements with its distributors and with pharmacies that prevented them from selling the drugs to the plaintiff. *Id.* at *6. The plaintiff brought Section 1 claims on grounds that the defendant's agreements with the distributors and pharmacies restrained trade by preventing generic competitors from filing ANDAs. *Id.* As the district court recognized, although the plaintiff had alleged the existence of agreements between the defendant and the distributors and pharmacies, the plaintiff did not allege that the distributors or pharmacies "shared [the defendant's] purpose . . . or that they had a common anticompetitive goal." *Id.* at *8. The district court entered judgment for the defendants, reasoning that there were no allegations that the distributors or pharmacies "stood to benefit from the alleged anticompetitive scheme," or even that they "had knowledge of [the defendant's] anticompetitive intent." *Id.*

no evidence of, and thus failed to prove, an anticompetitive agreement among the distributors to prevent generic competitors from acquiring product samples, or among the API suppliers to substantially foreclose generic competitors from acquiring a supply of pyrimethamine API. Such so-called "rimless wheel" conspiracies are not actionable under the law of this Circuit. *See, e.g.*, *United States v. Apple, Inc.*, 791 F.3d 290, 314 n.15 (2d Cir. 2015) (plaintiff must "prove the existence of a 'rim' to the wheel in the form of an agreement among the horizontal competitors"); *PepsiCo, Inc. v. Coca-Cola Co.*, 315 F.3d 101, 110 (2d Cir. 2002) (per curiam) (affirming the entry of summary judgment in favor of defendant where plaintiff "offered no evidence of direct communications" among the alleged spokes to the conspiracy).

In sum, because there is no evidence of joint or concerted action, Plaintiffs cannot prove a central element of their claim under Section 1 and its state-law analogues.

G. Plaintiffs Have Not Properly Defined a Relevant Market

Independent of their inability to establish that the challenged conduct caused any anticompetitive effects at all, Plaintiffs have also failed to meet their threshold burden of proving that Vyera has market power in a properly defined relevant market. *See Am. Express*, 138 S. Ct. at 2285 & n.7; *Hayden Publ'g Co.*, 730 F.2d at 68 (Plaintiffs "have the burden at trial of establishing the relevant product market.").

Here, Plaintiffs allege that the relevant product market consists of "FDA-approved pyrimethamine products." (Am. Compl. ¶ 300). Because the only FDA-approved pyrimethamine products are Daraprim and generic Daraprim, Plaintiffs' contention is that the relevant product market is limited to Daraprim and generic Daraprim.

Plaintiffs must establish that the outer boundaries of this proposed market are properly determined by the "reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *US Airways*, 938 F.3d at 64 (quoting *Brown*

Shoe Co. v. United States, 370 U.S. 294, 325 (1962)). "'Interchangeability' looks to the use or function of the given product as compared to other products." *Bayer Schering Pharma AG*, 813 F. Supp. 2d at 575 (citation omitted). "'Cross-elasticity' is related to interchangeability, and requires a consideration of the extent to which a change in the price of one product will alter demand for another product." *Id.* (citation omitted).

In the context of prescription drugs, courts assessing interchangeability look to the extent to which one drug has "similar effectiveness" and is therefore "readily substitutable" with another drug for the treatment of the underlying condition. *See, e.g.*, *Mylan Pharms. Inc.*, 838 F.3d at 435–36 (citation omitted); *accord Geneva Pharms. Tech. Corp.*, 386 F.3d at 496 (drugs that are "therapeutically equivalent" may be interchangeable with one another). Cross-elasticity analysis in prescription drug cases focuses on the extent to which a change in the price of one drug affects the demand for that drug, as well as for other drugs used to treat the same condition. *See, e.g.*, *Geneva Pharms. Tech. Corp.*, 386 F.3d at 496–99; *Mylan Pharms. Inc.*, 838 F.3d at 437.

Plaintiffs cannot meet their burden to establish that the relevant product market is properly defined because the evidence establishes that (1) at least two other drugs are substitutable for Daraprim or generic Daraprim for the treatment of toxoplasmosis—TMP-SMX (Bactrim) and compounded pyrimethamine, and (2) Vyera's increase of the price of Daraprim in August 2015 caused a sharp decline in sales of Daraprim and a concomitant rise in the use of other toxoplasmosis therapies, reflecting a high degree of cross-elasticity of demand.

Defendants provided medical and economic expert evidence through the testimony of Dr. Jena establishing both therapeutic interchangeability and cross-elasticity of demand. And even Plaintiffs' economic expert acknowledged that at least some of Daraprim's significant

"quantity loss is plausibly attributable to consumers switching to [Bactrim] or compounded pyrimethamine." (Hemphill Report ¶ 138).

Because Plaintiffs cannot meet their burden of showing that they have properly defined the relevant market, they also cannot meet their burden of showing that Vyera has market power or monopoly power in a properly defined relevant market. That failure is also fatal to Plaintiffs' claims.

H. Plaintiffs Have Not Demonstrated That an Injunction Is Needed to Remedy Ongoing Anticompetitive Conduct

Plaintiffs seek far-reaching injunctive relief, including, *inter alia*, that Defendants be "permanently enjoined from continuing their course of conduct," and "permanently enjoined from engaging in similar and related conduct in the future," and that Mr. Shkreli and Mr. Mulleady each be "permanently enjoined from owning in part or whole or working for a company engaged in the pharmaceutical industry." (Am. Compl. Prayer for Relief ¶¶ 13-15).

Injunctions are forward-looking remedies. *See W. T. Grant Co.*, 345 U.S. at 633. Thus, Plaintiffs must show that a permanent injunction is necessary—because harm to competition is ongoing or is likely to recur (in which case the injunction will stop it). *See id.*; *Abbvie Inc.*, 976 F.3d at 380.

All of Plaintiffs' evidence, however, concerns conduct that occurred in the past and that was allegedly intended to deter or delay generic competition to Daraprim. That ship has long since sailed. There are now four generic forms of Daraprim that have been approved by the FDA, two of which have been on the market for more than a year and a half. "Class of trade" provisions in Vyera's distribution agreements no longer have any arguable relevance to the ability of generic manufacturers to obtain prescription drug samples because brand manufacturers are now obligated by statute to sell samples directly to generic manufacturers.

See CREATES Act, Pub. L. No. 116-94, § 610 (enacted Dec. 20, 2019). Pyrimethamine API is available from multiple suppliers around the world—several of which have DMFs on file, and in any event, Vyera terminated its exclusive supply agreement with [redacted] in late 2019. *See* GX 1204. And the challenged provisions restricting the sale of Daraprim sales data in two of Vyera's distribution agreements were also terminated in 2019.

There is, in sum, no forward-looking purpose that an injunction could serve here. The recent *FTC v. Abbvie Inc.* case in the Eastern District of Pennsylvania is instructive on this point. *See* 329 F. Supp. 3d 98 (E.D. Pa. 2018). There, the FTC brought antitrust claims against defendant pharmaceutical manufacturers that the FTC alleged had filed two sham patent infringement lawsuits several years earlier in an effort to delay generic competition to a particular drug product. *Id.* at 106. Yet, there was no evidence that the defendants had filed any other sham lawsuits since then, or that they intended to do so in the future. *Id.* at 145. And, during the intervening period, generic versions of the drug product had entered the market. *Id.* On these facts, Judge Bartle declined to issue an injunction. *Id.* ("The FTC has proven that defendants filed two sham infringement lawsuits . . . . Nonetheless, the FTC has presented no evidence that defendants are currently violating antitrust laws or about to violate antitrust laws . . . . The fact that defendants filed two such lawsuits, without more, does not establish that defendants have a pattern or practice of doing so. On this record there is no basis to conclude that defendants' misconduct is likely to reoccur."). The Third Circuit subsequently affirmed Judge Bartle's decision not to award injunctive relief. *See Abbvie Inc.*, 976 F.3d at 380.

In the absence of any evidence that Defendants are engaged in ongoing misconduct or are likely to engage in misconduct in the future, the same result should obtain here.

I. The State Plaintiffs Have Not Shown They Are Entitled to Equitable Monetary Relief

The State Plaintiffs' request for the equitable monetary remedy of disgorgement requires them to establish when Defendants' alleged ill-gotten gains began to accrue. In cases alleging delayed generic competition, this requires establishment of a but-for entry date on which generic competition would have occurred but for the defendant's alleged anticompetitive conduct. *See* Areeda & Hovenkamp, § 2046g; *see also In re Lidoderm Antitrust Litig.*, 2017 WL 679367, at *28. As discussed above, Plaintiffs' economic expert does not provide such but for entry dates as part of his opinions. He simply purports to calculate ill-gotten gains based on "but for" entry dates provided by the speculative testimony of two of the generic manufacturers—Fera and Cerovene. Such speculative assumptions cannot support the State Plaintiffs' claim for equitable monetary relief, or this Court's calculation of any such remedy.

CONCLUSION

Plaintiffs cannot meet their threshold burdens of proving that the challenged conduct delayed generic competition in the alleged relevant market of "FDA-approved pyrimethamine products." Their inability to meet this burden is dispositive of all of Plaintiffs' claims.

In addition to their failure to prove liability, Plaintiffs have failed to prove that injunctive relief is necessary to remedy any ongoing or threatened future anticompetitive conduct.

Finally, Plaintiffs failed to establish that Defendants obtained—and thus are obligated to disgorge—any ill-gotten gains or excess profits.

Dated: October 20, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on October 20, 2021, a copy of the foregoing Defendants' Memorandum Addressing Questions of Law Expected to Arise at Trial was served upon all counsel of record.

/s/ Noah J. Kaufman